

AUG 29 2003

K031697

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PREMARKET NOTIFICATION
510(k) SUMMARY

1. *Submitter's Name:* Schering-Plough HealthCare Products, Inc.
Address: 3030 Jackson Avenue, Memphis, TN 38151
Telephone Number: (901) 320-2917
Contact Person: John M. Clayton, PhD
Date Prepared: August 8, 2003
2. *Device Name:*
Proprietary Name: Dr. Scholl's® Freeze Away™ Wart Remover
Usual Name: OTC Wart Removal System
Classification Name: Cryosurgical Unit, Accessories
3. *Devices to Which Substantial Equivalence is Claimed:*
Modification to Wartner Wart Removal System, by Wartner Medical Products
(Primary Predicate) – K011708
Histofreezer Wart Removal System, by OraSure Technologies, Inc. **(Plantar Wart Claim)** – K023487, K924114
4. *Description of Device:*
Dr. Scholl's Freeze Away Wart Remover is a cryosurgical system for the over-the-counter removal of common warts and plantar warts on the bottom of the foot. The device consists of the following:
 - a. Pressurized canister with a cryogen mixture of liquid dimethyl ether and propane
 - b. Reusable activator that releases the cryogen into the applicators
 - c. Disposable applicators
 - d. Information booklet
5. *Intended Use Statement:*
Dr. Scholl's Freeze Away Wart Remover is indicated for the over-the-counter removal of common warts and plantar warts on the bottom of the foot.
6. *Comparison of Technological Characteristics:*
Dr. Scholl's Freeze Away Wart Remover is substantially equivalent to the Modification to Wartner Wart Remover System by Wartner Medical Products. The only significant difference between the two products is that the Freeze Away Wart Remover product is additionally indicated for the removal of plantar warts. For the over-the-counter plantar wart indication, we are claiming substantial equivalence to the Histofreezer Wart Removal System.

All 3 devices (Freeze Away, Wartner, Histofreezer) are portable cryosurgical systems comprised of a canister containing cryogen and an applicator that is saturated with cryogen and then applied to the wart to be treated.

a. Laboratory Testing

The average temperature of the Dr. Scholl's Freeze Away Wart Remover applicator surface after saturation is -42°C and is similar to that of the predicate devices (see below).

b. Biocompatibility

The cryogen used is a mixture of dimethyl ether and propane, which is the same as the cryogen used in the primary predicate device (Wartner).

The standard biocompatibility studies recommended under ISO 10993 for a medical device with limited surface contact duration to breached/compromised skin were conducted on the applicator material and are included in this 510(k).

c. Comparison to Predicate Devices:

Application

Dr. Scholl's Freeze Away Wart Remover includes an applicator that is saturated with cryogen and then applied to the wart to be treated.

The primary predicate device (Wartner) uses a similar applicator constructed of a different material.

Applicator Effectiveness Duration

Dr. Scholl's Freeze Away Wart Remover maintains a temperature of -42°C at the applicator tip for approximately 170 seconds when tested using a temperature probe resting on a room temperature Teflon surface. A temperature of -57°C [similar to that listed in 510(k)s K011708 and K924114] is measured if tested using a temperature probe held in mid-air. The method that employs a Teflon surface under the temperature probe is a more appropriate method for simulation of actual use conditions and was used for the substantial equivalence comparison.

The primary predicate device (Wartner) maintains a similar temperature (-36°C) for approximately 75 seconds, while the Histofreezer device maintains the same temperature as Freeze Away (-42°C) for approximately 230 seconds. All devices maintain the freezing temperature for a sufficient length of time to allow the product to be used according to the instructions for use.

Cryogen

Dr. Scholl's Freeze Away Wart Remover uses a cryogen composed of dimethyl ether and propane.

The primary predicate device (Wartner) uses the same cryogen.

Safety / Ease of Use

Dr. Scholl's Freeze Away Wart Remover includes a safety feature whereby the cryogen will be released into the applicator only after the applicator is attached to the pressurized can and pressed onto the activator. The applicator on the Freeze Away product also contains a luer lock which allows the applicator to be twisted onto the can, preventing accidental detachment during activation or treatment.

The primary predicate device (Wartner) utilizes the first safety feature listed above but does not contain the second safety feature.

Indications for Use

Dr. Scholl's Freeze Away Wart Remover is indicated for the over-the-counter removal of common warts and plantar warts.

The primary predicate device (Wartner) is indicated for the over-the-counter removal of common warts, while a second predicate device (Histofreezer) is indicated for the over-the-counter removal of common warts and plantar warts.

Labeling

The labeling of Dr. Scholl's Freeze Away Wart Remover has been developed to ensure the consumer has adequate directions for safe use. Freeze Away labeling has also been developed to provide adequate information for the consumer to make a self diagnosis and to ensure that they contact their doctor if in any doubt, if stinging or aching persists after treatment, or if the wart does not improve after four treatments.

The safety and warning statements for the OTC predicate device (Modification to Wartner Wart Removal System) are essentially similar.

7. *Conclusion*

Based on the information presented above, it is concluded that the proposed Dr. Scholl's Freeze Away Wart Remover is safe and effective for its intended use when used in accordance with label directions and is substantially equivalent to the predicate devices.



AUG 29 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Philip Johnson
Manager, Regulatory Affairs
Schering-Plough Healthcare Products
3 Connell Drive
Berkeley Heights, New Jersey 07922

Re: K031697

Trade/Device Name: Dr. Scholl's® Freeze Away™ Wart Remover
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: May 30, 2003
Received: June 3, 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K031697

Device Name: Dr. Scholl's® Freeze Away™ Wart Remover

Indications for Use: For the over-the-counter removal of common warts and plantar warts on the bottom of the foot.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

Over-The-Counter Use ☒

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031697